

Center for Veterinary Medicine

Approvals with Letters Issued and Publications in the Federal Register

CRITERIA

Letter Date Range **From:** 10/01/1999 **To:** 09/30/2000 **Sort Order:** Letter Date Ascending **Count:** 53

Letter Date	Publish Date	Submission ID	Applicant	Chemical	Species	Approval Type	Summary	Team
10/04/99	11/24/99	N 141087 C 0012	FORT DODGE ANIMAL HEALTH DIVISION OF AMERICAN HOME PRODUCTS	MOXIDECTIN	EQUINE	NEW INDICATION	Supplemental approval for moxidectin to add new indication of "For the treatment and control of <i>Gasterophilus nasalis</i> (3rd instars)" and a labeling revision of the precautions section to read "This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result." The photograph on the carton was changed to remove the picture of a young foal.	HFV-112
10/22/99	12/07/99	A 200244 E 0005	PHARMACIA AND UPJOHN CO	SULFADIAZINE, TRIMETHOPRIM	EQUINE	ORIGINAL GENERIC	Original generic approval for sulfadiazine and trimethoprim for the control of bacterial infections of horses during treatment of acute strangles, respiratory tract infections, acute urogenital infections, wound infections, and abscesses.	HFV-102
11/02/99	06/09/00	N 141099 C 0008	FORT DODGE ANIMAL HEALTH DIVISION OF AMERICAN HOME PRODUCTS	MOXIDECTIN	BEEF CATTLE, DAIRY CATTLE	NEW SPECIES/CLASS	Supplemental approval for the addition of dairy cattle with a zero-day milk discard time and, thus, the removal of the warning statement for female dairy cattle of breeding age. Meat and milk produced from cattle treated with CYDECTIN Pour-On may now be used at any time following treatment.	HFV-135
11/03/99	12/17/99	N 140976 E 0002	PHARMACIA AND UPJOHN CO	NEOMYCIN SULFATE	BEEF CATTLE, MINOR RUMINANT, SWINE	DESI	DESI finalizations of neomycin sulfate for the treatment and control of colibacillosis (bacterial enteritis) caused by <i>Escherichia coli</i> susceptible to neomycin sulfate in cattle (excluding veal calves), swine, sheep and goats.	HFV-102
11/17/99	12/22/99	N 141103 E 0002	ABBOTT LABS	SEVOFLURANE	CANINE	NEW CHEMICAL ENTITY	Original approval for sevoflurane as an inhalant anesthetic for the induction and maintenance of anesthesia in dogs	HFV-114
11/29/99	07/06/00	N 032319 C 0045	FORT DODGE ANIMAL HEALTH DIVISION OF AMERICAN CYANAMID	FURAZOLIDONE	CANINE, EQUINE	NEW LIMITATION	Supplemental approval to withdraw indications for use of Furox (furazolidone) Aerosol Powder in cattle for the treatment of bacterial infections of bovine eye and for the treatment and to reduce the incidence of additional cases of infectious bovine keratoconjunctivitis (pink eye) caused by <i>Moraxella bovis</i> . This withdraws all approved indications for cattle. Notice is being held until the prohibited list can be revised to delete the exception for topical uses of nitrofurans.	HFV-216
11/29/99	02/29/00	N 140992 C 0021	HOECHST ROUSSEL VET	ESTRADIOL, TRENBOLONE ACETATE	BEEF CATTLE	NEW DOSAGE	Supplemental approval for trenbolone acetate and estradiol for increased rate of weight gain and improved feed efficiency in cattle fed in confinement for slaughter.	HFV-126
12/22/99	02/29/00	N 065480 R 0025	PENNFIELD OIL CO	CHLORTETRACYCLINE HYDROCHLORIDE	BEEF CATTLE, DAIRY CATTLE, SWINE	NEW TOLERANCE/WITHDRAWAL PERIOD	Supplemental approval to finalize the revision of the withdrawal period in swine to zero day for chlortetracycline for the control and treatment of bacterial enteritis (scours) caused by <i>Escherichia coli</i> and bacterial pneumonia associated with <i>Pasteurella</i> spp., <i>Actinobacillus pleuropneumoniae</i> (<i>Hemophilus</i> spp.) and <i>Klebsiella</i> spp. in swine and calves	HFV-102
12/22/99	01/26/00	N 140863 E 0076	ELANCO ANIMAL HEALTH CO	RACTOPAMINE HYDROCHLORIDE	SWINE	NEW CHEMICAL ENTITY	Original approval for ractopamine hydrochloride for increased rate of weight gain, improved feed efficiency, and increased carcass leanness in finishing swine fed a complete ration containing at least 16% crude protein from 150 lb (68 kg) to 240 lb (109 kg) body weight	HFV-128
12/23/99	07/07/00	N 141121 A 0000	ALPHARMA INC	BACITRACIN METHYLENE DISALICYLATE, ROXARSONE, SALINOMYCIN SODIUM	CHICKEN	ADAA, NEW COMBINATION, NEW SPECIES/CLASS	Original approval for salinomycin, BMD, roxarsone for the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> , as an aid in the prevention and control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in broiler, roaster, and replacement (breeder and layer) chickens	HFV-128

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01/11/00	04/18/00	N 141067 C 0014	BIOPURE CORP	HEMOGLOBIN GLUTAMER 200 (BOVINE)	CANINE	NEW DOSAGE	Supplemental approval for Hemoglobin glutamer-200 changes the original approval from a fixed dosage of 30 ml/kg to a flexible dosage range of 10-30 ml/kg in dogs	HFV-112
01/13/00	08/17/00	N 141090 E 0002	SCHERING PLOUGH ANIMAL HEALTH CORP	DICLAZURIL, VIRGINIAMYCIN	CHICKEN	ADAA, NEW COMBINATION	Original approval for diclazuril plus virginiamycin for the prevention of coccidiosis caused by Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mitis (mivati) and E. maxima, and for increased rate of gain and improved feed efficiency in broiler chickens	HFV-128
01/13/00	08/17/00	N 141153 A 0000	SCHERING PLOUGH ANIMAL HEALTH CORP	BACITRACIN METHYLENE DISALICYLATE, DICLAZURIL	CHICKEN	ADAA, NEW COMBINATION	Original approval for diclazuril plus bacitracin methylene disalicylate for the prevention of coccidiosis caused by Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mitis (mivati) and E. maxima, and for increased rate of gain and improved feed efficiency in broiler chickens	HFV-128
01/24/00	04/18/00	N 141162 A 0000	WELLMARK INTERNATIONAL	S-METHOPRENE	CANINE	NEW CHEMICAL ENTITY	Original approval for (S)-Methoprene for the prevention and control of flea populations in dogs, nine weeks of age or older and 4 pounds body weight or greater.	HFV-112
02/02/00	03/07/00	N 141146 A 0000	KOFFOLK INC	BACITRACIN ZINC, NICARBAZIN	CHICKEN	ADAA, NEW COMBINATION	Original approval for the combination of nicarbazin and bacitracin zinc as an aid in preventing outbreaks of cecal and intestinal coccidiosis, and for increased rate of weight gain and improved feed efficiency in broiler chickens	HFV-128
02/02/00	03/15/00	N 141163 A 0000	NOVARTIS ANIMAL HEALTH	MILBEMYCIN OXIME SOLUTION	FELINE	NEW DOSAGE FORM, NEW INDICATION	Original approval for milbemycin for the treatment of ear mite infestations in cats and kittens eight weeks of age and older	HFV-112
02/04/00	03/30/00	A 200275 E 0001	MED PHARMEX INC	TRIAMCINOLONE ACETONIDE	CANINE	ORIGINAL GENERIC	Original generic approval for triamcinolone acetoneide cream for topical treatment of allergic dermatitis and summer eczema in dogs.	HFV-102
02/04/00	04/18/00	N 097222 C 0066	FORT DODGE ANIMAL HEALTH DIVISION OF AMERICAN HOME PRODUCTS	CEPHAPIRIN SODIUM	BEEF CATTLE, DAIRY CATTLE	NEW TOLERANCE/WITHDRAWAL PERIOD	Supplemental approval to delete the milk withdrawal time for cephalirin sodium for the treatment of lactating cows having bovine mastitis caused by susceptible strains of Streptococcus agalactiae and Staphylococcus aureus	HFV-133
02/10/00	04/18/00	N 131675 C 0059	HOECHST ROUSSEL VET	FENBENDAZOLE	EXOTIC/ZOO/WILDLIFE, SWINE, TURKEY	NEW TOLERANCE/WITHDRAWAL PERIOD	Supplemental approval provides for the revision 21 CFR 556.275 by establishing tolerances for residues in swine liver and muscle and adding allowable daily intake (ADI). The drug is approved for the removal of: adult stage lungworms; adult and larvae (L3,4 stages- liver, lung, intestinal forms); large roundworms; adult stage nodular worms; small stomach worms; adult and larvae (L2,3,4 stages - intestinal mucosal forms) whipworms; adult and larvae kidney worms in swine.	HFV-135
03/06/00	05/09/00	A 200221 R 0027	IVY LABS INC	ESTRADIOL, TRENBOLONE ACETATE, TYLOSIN TARTRATE	BEEF CATTLE	NEW SPECIES/CLASS, TECHNICAL CORRECTION	Supplemental approval for the use of and ear implant with 40 mg of trenbolone acetate and 8 mg estradiol for the increased rate of weight gain in pasture cattle (slaughter, stocker, and feeder steers and heifers).	HFV-126
04/07/00	07/06/00	N 141144 A 0000	ALPHARMA INC	BACITRACIN METHYLENE DISALICYLATE, FENBENDAZOLE	SWINE	NEW COMBINATION	Original approval for the combined use of BMD and fenbendazole for the removal of lungworms, gastrointestinal worms, and kidneyworms in swine; and for increased rate of weight gain and improved feed efficiency and swine dysentery in growing and finishing swine; and for control of clostridial enteritis in pregnant swine 14 days before and 21 after farrowing.	HFV-135
05/09/00	07/06/00	N 128620 C 0081	HOECHST ROUSSEL VET	FENBENDAZOLE	BEEF CATTLE, MINOR RUMINANT	NEW TOLERANCE/WITHDRAWAL PERIOD	Supplement approval for fenbendazole to provide for the revision of 21 CFR 556.275 by establishing tolerances for residues in bovine and goat muscle.	HFV-135
05/24/00	06/28/00	P 005671 A 0000	NSRP 7	CEFTIOFUR SODIUM	MINOR RUMINANT	PUBLICATION OF AVAILABILITY OF DATA	Approval of Public Master File providing data and information to demonstrate effectiveness, target animal safety, and human food safety for the use of ceftiofur sodium injection for the treatment of goat respiratory disease (pneumonia) associated with Pasteurella (Mannheimia) haemolytica and/or Pasteurella multocida.	HFV-133

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05/26/00	07/24/00	N 141135 A 0000	ALPHARMA INC	ROXARSONE, SALINOMYCIN	CHICKEN	ADAA, NEW COMBINATION	Original combination approval for salinomycin and roxarsone as an aid in the prevention of coccidiosis caused by Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in roaster and replacement (breeder and layer) chickens.	HFV-128
06/13/00	07/26/00	A 200279 E 0001	ABBOTT LABS	KETAMINE HYDROCHLORIDE	FELINE	ORIGINAL GENERIC	Original approval for ketamine hydrochloride injection for restraint or as the sole anesthetic agent for diagnostic or minor, brief, surgical procedures that do not require skeletal muscle relaxation in cats. It may be used in subhuman primates for restraint.	HFV-102
06/13/00	07/21/00	N 141152 C 0002	PFIZER INC	SELALECTIN	CANINE, FELINE	NEW INDICATION	Supplemental approval for selamectin to add control of intestinal hookworm and roundworm infections in cats to existing claims of kills adult fleas and prevents flea eggs from hatching for one month and for prevention and control of flea infestations, prevention of heartworm disease caused by Dirofilaria immitis, and treatment and control of ear mite infestations in cats and dogs, and for treatment and control of sarcoptic mange and for the control of ticks in dogs	HFV-112
06/19/00	07/26/00	N 140897 C 0051	HOECHST ROUSSEL VET	ESTRADIOL, TRENBOLONE ACETATE	BEEF CATTLE	NEW DOSAGE	Supplemental approval for the administration of a dose of 80 mg trenbolone acetate and 16 mg estradiol for increased rate of weight gain and improved feed efficiency in steers fed in confinement for slaughter. (Note: The sponsor currently had an approved ear implant containing 120 mg trenbolone acetate and 24 mg estradiol (Revalor-S) - see 21 CFR 522.2477.)	HFV-126
06/19/00	07/26/00	N 140992 C 0020	HOECHST ROUSSEL VET	ESTRADIOL, TRENBOLONE ACETATE	BEEF CATTLE	NEW DOSAGE	Supplemental approval for the administration of a dose of 80 mg trenbolone acetate and 8 mg estradiol for increased rate of weight gain in heifers fed in confinement for slaughter. (Note: The sponsor currently has an approved implant containing 140 mg trenbolone acetate and 14 mg estradiol (Revalor - H) - see 21 CFR 522.2477.)	HFV-126
06/21/00	07/26/00	N 140988 C 0037	MERIAL LTD	IVERMECTIN	BEEF CATTLE	NEW INDICATION	Supplemental approval for ivermectin sustained release bolus to revise 21 CFR 520.1197(d)(2) by replacing "(approximately 135 days)" with "(approximately 130 days)" for the ivermectin delivery period. The IVOMECO SR Bolus is indicated for the control and treatment of established and new infection for roundworms, lungworms, mange mites, sucking lice, cattle grubs, and ticks in cattle.	HFV-135
06/26/00	08/04/00	P 005673 A 0000	NRSP 7	TILMICOSIN PHOSPHATE	MINOR RUMINANT	PUBLICATION OF AVAILABILITY OF DATA	Approval of Public Master File providing data demonstrating effectiveness and safety of tilmosin phosphate injection for the treatment of bacterial pneumonia due to Pasteurella (Mannheimia) haemolytica in sheep.	HFV-133
06/28/00	09/05/00	N 140955 E 0010	ELANCO ANIMAL HEALTH CO	BAMBERMYCINS, MONENSIN	TURKEY	ADAA, NEW COMBINATION, NEW SPECIES/CLASS	Original combination approval for monensin plus bambermycins For the prevention of coccidiosis caused by Eimeria adenoides, E. meleagrimitis, and E. gallopavonis, and for increased rate of weight gain, for improved feed efficiency and improved feed efficiency in growing turkeys.	HFV-128
06/28/00	07/26/00	N 140976 C 0007	PHARMACIA AND UPJOHN CO	NEOMYCIN SULFATE	BEEF CATTLE, MINOR RUMINANT, SWINE	NEW FORMULATION	Supplemental application for neomycin sulfate labels be changed from 400-1600 to 250-2250 g/ton of neomycin sulfate in complete feed. This change addresses the problem that the current level of 400 g/ton will overdose the young pigs and the 1600 g/ton will underdose the large sows. The new range of 250-2250 g/ton is the appropriate level for this neomycin medicated feed to provide for a dose of 10 mg neomycin sulfate per pound body weight per day for all swine.	HFV-102
06/28/00	09/05/00	N 141138 A 0000	ALPHARMA INC	BACITRACIN METHYLENE DISALICYLATE, MONENSIN, ROXARSONE	CHICKEN	ADAA, NEW COMBINATION, NEW SPECIES/CLASS	Original combination approval of monensin, BMD, and roxarsone as an aid in the prevention of coccidiosis caused by Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati, and E. maxima, as an aid in the prevention and control of necrotic enteritis caused or complicated by Clostridium spp. or other organisms susceptible to bacitracin, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in replacement chickens intended for use as cage layers.	HFV-128

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06/28/00	09/08/00	N 141139 A 0000	ALPHARMA INC	MONENSIN, ROXARSONE	CHICKEN	ADAA, NEW COMBINATION, NEW SPECIES/CLASS	Original combination approval for monensin and roxarsone as an aid in the prevention of coccidiosis caused by Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati, and E. maxima, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in replacement chickens intended for use as cage layers.	HFV-128
07/03/00	09/05/00	A 200289 E 0001	MED PHARMEX INC	NEOMYCIN SULFATE	BEEF CATTLE, MINOR RUMINANT, SWINE	ORIGINAL GENERIC	Original generic approval for neomycin sulfate for the treatment and control of colibacillosis (bacterial enteritis) caused by Escherichia colic susceptible to neomycin sulfate in cattle (excluding veal calves), swine, sheep and goats.	HFV-102
07/03/00	08/22/00	N 131675 C 0067	HOECHST ROUSSEL VET	FENBENDAZOLE	EXOTIC/ZOO/WILDLIFE, SWINE, TURKEY	NEW INDICATION, NEW SPECIES/CLASS	Supplemental approval for fenbendazole for the removal and control of gastrointestinal worms: round worms, adults and larvae (Ascaridia dissimilis); cecal worms, adults and larvae (Heterakis gallinarum), an important vector of Histomonas meleagridis (Blackhead) in growing turkeys.	HFV-135
07/03/00	08/22/00	N 141155 A 0000	ALPHARMA INC	BACITRACIN METHYLENE DISALICYLATE, ROBENIDINE HYDROCHLORIDE, ROXARSONE	CHICKEN	ADAA, NEW COMBINATION	Original approval for robenidine hydrochloride, bacitracin methylene disalicylate, roxarsone as an aid in the prevention of coccidiosis caused by Eimeria mivati, E. brunetti, E. tenella, E. acervulina, E. maxima, and E. necatrix, as an aid in the prevention and control of necrotic enteritis caused or complicated by Clostridium spp. or other organisms susceptible to bacitracin, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in broiler chickens.	HFV-128
07/03/00	07/25/00	N 141157 A 0000	ALPHARMA INC	HALOFUGINONE HYDROBROMIDE, ROXARSONE	CHICKEN	ADAA, NEW COMBINATION	Original approval for halofuginone hydrobromide plus roxarsone for the prevention of coccidiosis caused by Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati, and E. maxima, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in broiler chickens, replacement caged laying chickens and replacement broiler breeder chickens, and an additional species of E. mitis in replacement caged laying chickens and replacement broiler breeder chickens	HFV-128
07/03/00	08/17/00	N 141158 A 0000	SCHERING PLOUGH ANIMAL HEALTH CORP	BAMBERMYCINS, DICLAZURIL	CHICKEN	ADAA, NEW COMBINATION	Original approval for diclazuril plus bambermycins for the prevention of coccidiosis caused by Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mitis (mivati) and E. maxima and for increased rate of weight gain and improved feed efficiency in broiler chickens.	HFV-128
07/03/00	09/05/00	N 141164 A 0000	ELANCO ANIMAL HEALTH CO	MONENSIN, TYLOSIN PHOSPHATE	CHICKEN	ADAA, NEW COMBINATION	Original approval for monensin plus tylosin phosphate as an aid in the prevention of coccidiosis caused by Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati, and E. maxima, and for increased rate of weight gain and improved feed efficiency in broiler chickens.	HFV-128
07/07/00	07/26/00	N 046699 C 0145	ALPHARMA INC	CHLORTETRACYCLINE	BEEF CATTLE, CHICKEN, MINOR RUMINANT, SWINE, TURKEY	NEW INDICATION	Supplemental application for chlortetracycline to add the claim for the control of porcine proliferative enteropathies (ileitis) associated with Lawsonia intracellularis susceptible to chlortetracycline in swine.	HFV-133
07/07/00	07/26/00	N 095735 C 0253	ELANCO ANIMAL HEALTH CO	MONENSIN SODIUM	BEEF CATTLE	NEW SPECIES/CLASS	Supplemental approval for Free Choice Monensin Mineral Granules Type C Medicated Feed to add the claim "for the prevention and control of coccidiosis caused by Eimeria bovis and E. zuernii" to the label.	HFV-135
07/07/00	09/08/00	N 141059 C 0007	ALPHARMA INC	BACITRACIN METHYLENE DISALICYLATE, CHLORTETRACYCLINE	SWINE	NEW INDICATION	Supplemental approval for chlortetracycline and bacitracin methylene disalicylate for increased rate of weight gain and improved feed efficiency and treatment of bacterial enteritis caused by E. coli and S. choleraesuis and bacterial pneumonia caused by P. multocida susceptible to chlortetracycline and for the control of porcine proliferative enteropathies (ileitis) caused by L. intracellularis. This adds the indication for the control of porcine proliferative enteropathies.	HFV-133

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08/07/00	09/15/00	N 140865 E 0007	ROCHE VITAMINS INC	BACITRACIN ZINC, NARASIN	CHICKEN	ADAA, NEW COMBINATION	Original combination approval for MONTEBAN and BACIFERM the prevention of coccidiosis caused by Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati and E. maxima, and for increased rate of weight gain and improved feed efficiency in broiler chickens.	HFV-128
09/07/00	10/16/00	A 200271 E 0002	AGRI LABS LTD	LEVAMISOLE PHOSPHATE	BEEF CATTLE	ORIGINAL GENERIC	Original generic approval for levamisole phosphate for the treatment of nematode infections with Stomach Worms (Haemonchus, Ostertagia, Trichostrongylus), Intestinal Worms (Trichostrongylus, Cooperia, Nematodirus, Bunostomum, Oesophagostomum, Chabertia), and Lungworms (Dictyocaulus) in cattle.	HFV-102
09/07/00	10/16/00	N 141036 C 0031	PHARMACIA AND UPJOHN CO	PIRLIMYCIN HYDROCHLORIDE	DAIRY CATTLE	NEW INDICATION	Supplemental approval for pirlimycin hydrochloride for the treatment of clinical and subclinical mastitis in lactating dairy cattle. Changes include (1) formulation change from gel to a sterile product, (2) reduction in the pre-slaughter withdrawal period from 28 days to 9 days, (3) removal of reference to the number of milkings, and (4) addition of ADI (0.01 mg/kg BW), and muscle tolerance (0.3 ppm).	HFV-133
09/18/00	11/27/00	A 200221 C 0035	IVY LABS INC	ESTRADIOL, TRENBOLONE ACETATE, TYLOSIN TARTRATE	BEEF CATTLE	NEW INDICATION	Supplemental approval for trenbolone acetate, estradiol and tylosin tartrate for increased rate of weight gain in pasture cattle (slaughter, stocker, and feeder steers and heifers). This supplement provides for the addition of a tylosin tartrate pellet as a local antibacterial to Component TE-G.	HFV-126
09/20/00	11/27/00	A 200286 E 0002	PHOENIX SCIENTIFIC INC	IVERMECTIN	EQUINE	ORIGINAL GENERIC	Original generic approval for ivermectin for the treatment of Large Strongyles, Small Strongyles, Pinworms, Roundworms, (Ascarids), Hairworms, Neck Threadworms, Largemouth Stomach Worms, Lungworms, Intestinal Threadworms and Bots and summer sores caused by Habronema and Draschia spp cutaneous third-stage larvae, and dermatitis caused by neck threadworm microfilariae in horses.	HFV-102
09/20/00	11/28/00	N 141136 A 0000	ALPHARMA INC	BACITRACIN METHYLENE DISALICYLATE, SALINOMYCIN	CHICKEN	ADAA, NEW COMBINATION	Original combination approval for salinomycin plus bacitracin MD for the prevention of coccidiosis caused by Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti, and E. mivati, and weight gain and feed efficiency for roaster and replacement (breeder and layer) chickens and as an aid in the control of necrotic enteritis caused or complicated by Clostridium spp. or other organisms susceptible to bacitracin in broiler, roaster, and replacement (breeder and layer) chickens.	HFV-128
09/20/00	11/01/00	N 141170 A 0000	ELANCO ANIMAL HEALTH CO	NARASIN, TYLOSIN PHOSPHATE	CHICKEN	ADAA, NEW COMBINATION	Original combination approval for Narasin (MONTEBAN) plus Tylosin phosphate (TYLAN) for the prevention of caused by Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati, and E. maxima, and for increased rate of weight gain and improved feed efficiency in broiler chickens.	HFV-128
09/26/00	11/07/00	A 200282 E 0002	FARNAM COMPANIES INC	PYRANTEL TARTRATE	EQUINE	ORIGINAL GENERIC	Original generic approval for pyrantel tartrate for the prevention of Strongylus vulgaris larval infections and for the control of LARGE STRONGYLES (adults) S. vulgaris, S. edentatus, Triodontophorus spp.; SMALL STRONGYLES (adult and forth-stage larvae) Cyathostomum spp. Cylicocyclus spp., Cylicostephanus spp., Cylicodontophorus spp., Poteriostomum spp.; PINWORMS (adult and fourth-stage larvae) Oxyuris equi; and ASCARIDS (adult and fourth-stage larvae) Parascaris equorum in horses.	HFV-102
09/29/00	11/07/00	N 141147 A 0000	ALPHARMA INC	CHLORTETRACYCLINE, DECOQUINATE	BEEF CATTLE	ORIGINAL GENERIC	Original approval of decoquinatate and chlortetracycline in combination in cattle feed for the prevention of coccidiosis caused by Eimeria bovis and E. zuernii; for the treatment of bacterial enteritis caused by Escherichia coli; for bacterial pneumonia caused by Pasteurella multocida susceptible to chlortetracycline in calves, beef and non-lactating dairy cows.	HFV-135
09/29/00	11/07/00	N 141176 A 0000	BAYER CORP	ENROFLOXACIN, SILVER SULFADIAZINE	CANINE	NEW COMBINATION, NEW INDICATION	Original approval for enrofloxacin /silver sulfadiazine otic antimicrobial emulsion for the treatment of canine otitis externa complicated by bacterial and fungal organisms susceptible to enrofloxacin and/or silver sulfadiazine in dogs.	HFV-112